FSN Ref: FSCA_EGFR_MULTI_01_2025
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Date: 21. 03. 2025

Urgent Field Safety Notice
gb ONCO EGFR

For Attention of*: Customers and distributors.

Contact details of local representative	
Name of local representative:	Jitka Kašparová
e-mail:	jitka.kasparova@generi-biotech.com
phone:	+420 734 334 449
Manufacturer address:	GENERI BIOTECH s.r.o. U Fotochemy 1763 500 02 Hradec Králové – Pražské Předměstí

A. Information on Affected Devices*	
1.	Device Type(s)*
	IVD kit, non-sterile
2.	Commercial name(s)
	gb ONCO EGFR
3.	Unique Device Identifier(s) (UDI-DI)
	N/A
4.	Primary clinical purpose of device(s)*
	gb ONCO EGFR diagnostic kit enables detection of EGFR mutations in exons 18, 19, 20 and 21 in cancer patients.
5.	Device Model/Catalogue/part number(s)*
	3282-024
6.	Software version
	N/A
7.	Affected serial or lot number range
8.	200104005
9.	Associated devices
	N/A

B. Reason for Field Safety Corrective Action (FSCA)*	
1.	Description of the product problem*
	When individual reactions are prepared, patient outcomes cannot be evaluated, the analysis is non-valid.
2.	Hazard giving rise to the FSCA*
	Invalid analysis, delay in results release
3.	Probability of problem arising
	The probability is very high. Invalid analysis only occurs if the kit is used to prepare individual reactions (for each patient). Once the kit is used once for all 24 reactions, the analysis is valid and correct results are obtained.
4.	Predicted risk to patient/users
	Delay in results release.
5.	Further information to help characterise the problem
	N/A
6.	Background on Issue
	Customer complaint.
7.	Other information relevant to FSCA
	N/A

C.

D. Type of Action to mitigate the risk*

1.	**Action To Be Taken by the User***	
	☒ Identify Device ☐ Quarantine Device ☒ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None *Provide further details of the action(s) identified.* Do not use the kit to prepare single reactions.	
2.	By when should the action be completed?	Immediately.
3.	Particular considerations for:	IVD
	Is follow-up of patients or review of patients' previous results recommended? *Provide further details of patient-level follow-up if required or a justification why none is required*	No

4.	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
5.	**Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None *Provide further details of the action(s) identified.*	
6.	By when should the action be completed?	31. 03. 2025
7.	Is the FSN required to be communicated to the patient /lay user?	No
	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	Not assigned for this FSN

	E. General Information*		
1.	FSN Type*		New
2.	For updated FSN, reference number and date of previous FSN		N/A
3.	For Updated FSN, key new information as follows		N/A
4.	Further advice or information already expected in follow-up FSN? *		No
5.	If follow-up FSN expected, what is the further advice expected to relate to:		N/A
6.	Anticipated timescale for follow-up FSN		N/A
7.	Manufacturer information (For contact details of local representative refer to page 1 of this FSN)		
	a. Company Name	**GENERI BIOTECH s.r.o.**	
	b. Address	**U Fotochemy 1763** **500 02 Hradec Králové – Pražské Předměstí**	
	c. Website address	**www.generi-biotech.com**	
8.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *		
9.	List of attachments/appendices:	N/A	
10.	Name/Signature	**Mgr. Jitka Kašparová, Ph.D.** Digitálně podepsal Jitka Kašparová Datum: 2025.03.21 00:06:34 +01'00'	

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.